

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESale PRICE	)	
LITIGATION	)	MDL No. 1456
_____	)	Civil Action No. 01-12257-PBS
	)	
<b>THIS DOCUMENT RELATES TO:</b>	)	Hon. Patti Saris
<i>United States of America ex rel. Ven-a-Care of</i>	)	
<i>the Florida Keys, Inc. v. Abbott Laboratories,</i>	)	
<i>Inc., Civil Action No. 06-11337-PBS</i>	)	Magistrate Judge Marianne B. Bowler
	)	

**UNITED STATES' SUR-REPLY TO ABBOTT'S REPLY TO THE OPPOSITION  
TO ABBOTT'S MOTION TO ENFORCE THE FEB. 16, 2007 PROTECTIVE ORDER  
AND FOR THE RETURN OF INADVERTENTLY PRODUCED DOCUMENTS**

The United States submits this Sur-reply to Abbott's Reply ("Reply") to the Government's Opposition ("Opposition") to Abbott's Motion to Enforce the February 16, 2007 Protective Order and For Order Compelling Plaintiff to Return Inadvertently Produced Privileged Documents (D.E. 5276)("Motion") to address several points in Abbott's Reply that raise new facts and arguments.

**ADDITIONAL FACTUAL BACKGROUND**

Since the United States filed its Opposition to Abbott's Motion on June 2, 2008, several matters have emerged that bear upon this Court's evaluation of Abbott's position. First, Abbott has now submitted an affidavit by its counsel Laura Dahl (Reply Exh. A, "Dahl Aff."), explaining that not only were the two copies of the Albrecht 1991 Memo (and the Albrecht Fax Cover) subjected to the two-tier attorney privilege review, they were also reviewed independently by another Abbott lawyer who evaluated the documents applying the Protective Order criteria before marking them "confidential." Ms. Dahl does not describe the actual criteria used to determine whether Abbott would designate the documents as confidential, nor does she explain how *yet another lawyer* could "inadvertently" miss the alleged privileged character of

the three documents while permitting their disclosure with a “confidential” designation. In short, Abbott completely fails to explain how an attorney specifically tasked with applying the Protective Order criteria could have overlooked the issue of whether the documents were also privileged.

Second, despite repeated requests over the course of discovery for clarification as to whether Abbott will assert an advice-of-counsel defense, Abbott has still not stated whether or not it will do so *at trial*. Abbott’s Reply, for the *first* time, states that defendant has not *yet* asserted an advice of counsel defense.<sup>1</sup> Until it filed its Reply, Abbott had never even stated this limited clarification. Regardless of whether Abbott has formerly pled an advice-of-counsel defense, the Government is entitled to know, for discovery purposes, whether Abbott will assert this defense at trial or at any future point in this case. Abbott has simply refused to answer this basic question and has declined to say even when it expects to make this decision.

Third, after filing its Opposition, the United States deposed Abbott’s former President and Chief Operating Officer, Richard Gonzalez, whose testimony stressed the involvement of the General Counsel’s office in compliance and Medicare and Medicaid regulatory matters. He also explained his own extensive reliance upon, or deferral to, the in-house counsel’s office with regard to decision-making concerning compliance issues that lie at the center of this lawsuit. (*See e.g.*, Exhibit “1” hereto, Gonzalez Dep. at pp. 100-102, 113-119, 123-127, 157-158, 179-181, 341, 348-349, 358-361, 377-378, 416-420, 434-442, 475-476).

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<sup>1</sup> At the depositions of Abbott witnesses, Abbott’s trial lawyers blocked questions by the United States which sought to probe to testimony that Abbott personnel relied upon counsel as part of their compliance efforts and attempts to act in good faith by instructing witnesses to refrain from answering based on privilege.

## ARGUMENT

### I. ABBOTT’S REPLY MISSTATES THE REQUIREMENTS FOR IMPLIED WAIVER

In its Reply, Abbott conflates direct waiver, which is the actual disclosure of privileged information, with implied waiver. Abbott heavily relies upon Third Circuit’s rigid criteria in *Rhone-Poulenc Rorer, Inc. v. Home Indem. Co.*, 32 F.3d 851 (3d Cir. 1994), and related cases, while casting aside controlling authority in this district and the First Circuit. See Opposition at pp. 8-9; *In Re Keeper of Records, XYZ Corp.*, 348 F.3d 16, 24 (1<sup>st</sup> Cir. 2003); *In re PolyMedica Corp. Securities Litigation*, 235 F.R.D. 28, 32 (D. Mass. 2006); *Rivera v. Kmart*, 190 F.R.D. 298, 304 (D.P.R. 2000); *Sax v. Sax*, 136 F.R.D. 542, 543-44 (D. Mass. 1991); see also, *U.S. v. Desir*, 273 F.3d 39, 45 (1<sup>st</sup> Cir. 2001)(decision of district court finding implied waiver was not clearly erroneous). The First Circuit has not adopted the more stringent *Rhone* standards.

This lawsuit concerns Abbott’s compliance with Medicare and Medicaid statutes, regulations and guidance. Abbott appears to argue that under *Rhone* as long as its affirmative defenses do not expressly use the exact words “advice-of-counsel” then its privileged communications have not been put at issue. This argument fails in light of testimony from Abbott employees concerning their reliance upon counsel to guide their actions and their assumption that Abbott’s Hospital Products Division’s (HPD’s) practices and procedures were in compliance with applicable laws and regulations.

As set forth in the Opposition, Abbott’s Rule 30(b)(6) designee repeatedly referred to documents produced shortly before his deposition that were prepared by counsel. Moreover Abbott’s general counsel, who also served as the company’s compliance officer, had exclusive control over compliance determinations. When answering what the HPD employees would do

with compliance questions, the Rule 30(b)(6) deponent made clear that “[t]hey would come to Legal . . . . They should not have gone to any other source other than Legal.” (Opposition Exhibit E, Fishman 3/12/08 Rule 30(b)(6) Dep. 312:4-22; 315:20-22; 316:1-4). Abbott has not advised the United States or the Court that it will not attempt to introduce these documents for any purpose, including in support of its Seventh and Tenth affirmative defenses<sup>2</sup>.

Abbott’s Reply does not deny that, when asked what Abbott’s compliance efforts were, or how the witnesses knew Abbott’s conduct did not violate Medicare or Medicaid, each key witness stated that he or she relied upon Abbott’s in-house counsel or Ms. Tobiason, who herself deferred to in-house counsel. (*See* Opposition at 10-11). Mr. Gonzalez provided similar testimony regarding the basis for his understanding of HPD compliance with Medicare and Medicaid and the legality of the HPD business practices. (*See* Sur-Reply Exhibit “1”, Gonzalez Dep. 100-102, 113-119, 123-127, 157-158, 341, 348-349, 358-361). To date, Abbott has not stated whether it will rely upon the testimony of these witnesses for any purpose in defending this action.

Abbott’s Reply also attempts to differentiate between the Albrecht 1991 Memo and the Albrecht Fax Cover by arguing that the documents Abbott relied upon at the Rule 30(b)(6) deposition were widely-distributed general training materials. Abbott offers no evidentiary basis for this assertion. Despite Abbott’s argument to the contrary, the documents produced by Abbott and relied upon by its Rule 30(b)(6) designee provide detailed and specific advice about

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<sup>2</sup>Abbott’s Tenth Affirmative Defense asserts that Abbott “has complied with all applicable regulations of the federal and state governments.” (*See* Abbott Answer, D.E. 5188, at p. 37). Abbott’s Seventh Affirmative Defense asserts that Abbott acted in good faith. *Id.*

compliance with federal and state laws.<sup>3</sup> Many of the documents appear to have had limited distribution, with some pertaining only to the Hospital Products Division or to the Home Infusion Business Unit, i.e. the same business unit at issue in the Albrecht 1991 Memo. (*See* Opposition Exhibit F). As set forth more fully in the Government's Opposition, Abbott cannot pick and choose which attorney-generated documents it wants to use to demonstrate compliance on one hand, while withholding other attorney instructions to employees on the same subject matter, on the other hand. Whether the materials received broad, or limited, distribution within the company, the fact is undisputed that compliance directives came from the general counsel/compliance officer's office. (Opposition at pp. 5-7).

## II. ABBOTT HAS FAILED TO DEMONSTRATE THAT THE ALBRECHT 1991 ADVICE WAS GIVEN AS ATTORNEY ADVICE AND NOT BUSINESS ADVICE

Abbott's Reply still fails to meet the requirement of showing that the Albrecht 1991 Advice was given by an in-house lawyer as attorney-client advice and not business advice. (*See* Opposition at p. 6). As recognized in this district, the requirement that a party invoking the privilege prove that the advice of an in-house lawyer is actually attorney-client privileged legal advice cannot be met simply by stating as much in a motion or other filing. "Merely saying that [the attorney] was so acting [in a legal, non-business capacity] is patently insufficient to meet this burden", and it will not be assumed that an in-house counsel is giving legal advice. *Borase v. M/A COM, Inc.*, 171 F.R.D. 10, 14 (D. Mass. 1997). The fact that an in-house counsel holds a

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<sup>3</sup> Abbott also tries to characterize the Albrecht 1991 Memo as unique claiming that it related to a Marketing Agreement, and not a Home Infusion consignment agreement. The United States has been unable to explore this purported distinction given that when it attempted to question the witness about the document, it was foreclosed from doing so by the "snapback" of the Albrecht 1991 Memo and Abbott's counsel's instructions. At any rate, this attempted differentiation is of no moment given that the Albrecht 1991 Memo, on its face, extends beyond a single contract and references broader advice and historic practices. (Opposition at pp. 12-14 (under seal)).

law degree does not automatically protect every communication. *Rivera v. Kmart Corp.*, 190 F.R.D. 298, 302-03 (D. P.R. 2000). Rather, the party asserting the privilege, must make a “clear” showing that the in-house counsel was given legal and not business advice. *Borase*, 171 F.R.D. at 14.

Abbott has completely failed to delineate how and when its general counsel stepped out of a role as legal counselor and into that of compliance officer. This failure, alone, should be fatal to its motion.

### III. ABBOTT FAILS TO SHOW THAT ITS DISCLOSURE OF THE ALBRECHT 1991 MEMO AND FAX COVER WERE NOT GROSSLY NEGLIGENT

According to Abbott, after it produced the documents at issue in discovery, “as the attorneys representing the Government must know, they had an ethical obligation to inform Abbott that they were in possession of the Privileged Documents.” Reply at 3. This statement in Abbott’s brief proves the Government’s point regarding the competency of Abbott’s privilege and confidentiality reviews. Abbott cannot credibly claim that Government attorneys should have recognized, from the face of these documents, that they were privileged without effectively damning its own review process.<sup>4</sup>

Once again, in its Reply Abbott points to its “two-tier” review process to demonstrate why its conduct in disclosing the Albrecht 1991 Memo and Fax Cover was not grossly negligent. It offers no counter to the authority cited by the United States for the proposition that the mere

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<sup>4</sup> Abbott’s suggestion that Government counsel committed an ethical breach with respect to the handling of the documents is inexplicable. The issue here is *not* whether Government counsel should have recognized that the documents originated with attorneys. As noted above, Abbott has both produced other attorney documents and allowed deposition questioning on those documents without trying to snap them back. What Abbott fails to explain is why a Government lawyer should have expected that Abbott would view the documents which are the subject of its motion any differently from the other attorney-generated documents which have been produced by the defendant.

existence of a review process does not explain how it prevented its gross negligence in failing to recognize the documents through that process, especially when not one, but two copies, of the Albrecht 1991 Memo were not flagged by attorneys conducting the two-tier privilege review.

Further, Abbott's Reply only bolsters and emphasizes its gross negligence by explaining for the *first* time that, in fact, each of these documents was subjected to review by a third attorney for confidentiality. It is incredible that an attorney confidentiality review – even if it was performed at a minimal level of competence – would not have flagged the possibly privileged character of these documents. Abbott's Reply impugns a Government lawyer for not identifying the Albrecht 1991 Memo and Fax Cover as privileged and immediately informing Abbott's counsel. Yet, Abbott itself – the party in the best position to recognize and understand the content of the documents – failed to do so despite three attorney reviews.

Recently, in *Victor Stanley, Inc. v. Creative Pipe, Inc.*, — F.Supp.2d —, 2008 WL 2221841, at \*7-8 (D. Md., May 29, 2008), the district court held that so-called inadvertent electronic production of privileged documents constituted a waiver as the party asserting the privilege failed to meet its burden in demonstrating that its electronic search was reasonable and sufficient to identify privileged documents. The *Victor Stanley* court concluded that the party asserting the privilege failed to take reasonable precautions to prevent the disclosure of electronically produced documents, including conducting a complete and proper computer search with relevant terms<sup>5</sup>. *Id.* Here, Abbott readily admits that it never even bothered to conduct a such a search prior to its electronic production. Coupled with Abbott's failure to

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<sup>5</sup> The court in *Victor Stanley* also cited to the one week delay between the production by the party asserting privilege and the discovery by the opposing party as dispositive, holding that it was “a period during which the Defendants failed to discover the disclosure.” *Victor Stanley*, 2008 WL 2221841, at \* 8. Here, more than four months elapsed between production and discovery by the Government, and Abbott still did not locate the document.

thrice identify the privileged character of the documents through attorney inspections of the documents, Abbott's conduct was grossly negligent.

WHEREFORE, for the forgoing reasons, and for those reasons set forth in the United States' Opposition, the United States respectfully requests that this Court deny Abbott's Motion to Enforce the February 16, 2007 Protective Order And For Order Compelling Plaintiff To Return Inadvertently Produced Privileged Documents, and order the production of all documents that refer, relate or pertain to Abbott's in-house counsel's advice concerning: all state and federal compliance or regulatory matters; General Counsel documents pertaining to Medicare or Medicaid and/or the Subject Drugs; the General Counsel's role as Compliance Officer; or, Abbott's business dealings and pricing that refer, relate or pertain to federal and state statutes, regulations and guidance for the time period of this case.



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**CERTIFICATE OF SERVICE**

I hereby certify that I have this day caused a redacted electronic copy of the above Sur-Reply to Abbott's Reply to the Opposition to Abbott's Motion to Enforce the Feb.16, 2007 Protective Order And For Return of Inadvertently Produced Documents to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Ann. M. St. Peter-Griffith

Dated: July 2, 2008